Supreme Court, U. S.
FILED
JUL 7 1980
MICHAEL RODAK, JR., CLERK

No. 80-23

IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

RICHARD SEELIG, TERRY HAWKINS
and DONALD PRIMMER,
Petitioners

v.

UNITED STATES OF AMERICA,
Respondent

PETITION FOR WRIT OF CERTIORARI TO UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

DANA G. RINEHART
MATAN, RINEHART & SMITH
261 South Front Street
Columbus, Ohio 43215
(614) 228-2678

Counsel for Petitioners

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTIONS PRESENTED

1. WHETHER THE DISPENSING OF A SCHEDULE IV OR V CONTROLLED SUBSTANCE BY A LICENSED PHARMACIST IN VIOLATION OF 21 C.F.R. §§ 1306.22, 1306.23, OR 1306.32 CAN BE CRIMINALLY PUNISHED UNDER 21 U.S.C. § 841(a)(1) OF THE FEDERAL CONTROLLED SUBSTANCES ACT.

2. WHETHER OR NOT A D.E.A. COMPLIANCE INVESTIGATOR CAN TESTIFY ON THE LAW, UNDER RULES 403, 702 and 704 OF THE FEDERAL RULES OF EVIDENCE, IN A PROSECUTION UNDER THE FEDERAL CONTROLLED SUBSTANCES ACT.

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PETITION FOR WRIT OF CERTIORARI TO UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

To the Honorable, the Chief Justice and Associate Justices of The Supreme Court of the United States:

Richard Seelig, Terry Hawkins and Donald Primmer, Petitioners herein, pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Sixth Circuit entered in the above-entitled case on May 8, 1980.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit is unreported and is printed in the Appendix hereto, *infra*, page 19a. The judgment of the United States Court of Appeals for the Sixth Circuit is printed in the Appendix hereto, *infra*, page 37a. The

Judgments and Probation/Commitment orders of the United States District Court for the Southern District of Ohio, Eastern Division are printed in the Appendix hereto, *infra*, page 39a.

JURISDICTION

The judgment of the United States Court of Appeals of the Sixth Circuit (Appendix, *infra*, page 37a) was entered on May 8, 1980. On May 27, 1980, Mr. Justice Stewart granted Petitioners an Order Extending Time to File Petition for Writ of Certiorari up to and including July 7, 1980 (Appendix, *infra*, page 45a). The jurisdiction of the Supreme Court is invoked under the provisions of Title 28, United States Code, Section 1254(1).

STATUTES AND REGULATIONS

21 U.S.C. § 801
21 U.S.C. § 802(10)
21 U.S.C. § 802(20)
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21 U.S.C. § 829
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21 U.S.C. § 842
21 U.S.C. § 871

21 C.F.R. § 1306.04(a)
21 C.F.R. § 1306.22
21 C.F.R. § 1306.23
21 C.F.R. § 1306.32

Rule 403, Federal Rules of Evidence
Rule 702, Federal Rules of Evidence
Rule 704, Federal Rules of Evidence

STATEMENT OF THE CASE

A. Statement of the Proceedings Below

The Grand Jury returned an indictment against Petitioners Richard Seelig, Terry Hawkins, and Donald Primmer, on February 5, 1979, for 165 counts of knowingly or intentionally and unlawfully distributing without a prescription within a 48-hour period more than four ounces of Robitussin A/C, Terpin Hydrate-Codeine, or Histadyl E/C, preparations containing not more than 200 milligrams of codeine per 100 milliliters as prohibited by 21 C.F.R. § 1306.32 and, therefore, in violation of 21 U.S.C. § 841(a)(1).

Additionally, the indictment charged all three Petitioners with 6 counts (Counts 168, 169, 171, 172, 173, and 174) and Richard Seelig and Terry Hawkins with 3 additional counts (Counts 166, 167, and 170) each, of knowingly or intentionally and unlawfully distributing a Schedule IV substance (Valium or Darvon) by unlawfully refilling a prescription in violation (ostensibly) of 21 U.S.C. § 841(a)(1).

Pre-trial discovery took place and Petitioners were granted leave to file a motion to dismiss.

Petitioners' motion to dismiss was denied on April 16, 1979.

On April 17, 1979, petitioners' motion in limine to exclude certain evidence was granted in part and denied in part, the Court ruling that a Sales Comparison Chart would be properly admitted at trial, but a Profit Comparison Chart would be excluded.

On that same day jury trial commenced in the United States District Court for the Southern District of Ohio, Eastern Division, before the Honorable Judge Joseph P. Kinneary.

The case was litigated for six days and on April 26, 1979, the jury began its deliberations. On April 27, 1979, the jury reached its verdicts and found Petitioner Richard Seelig guilty of 19 misdemeanors and 8 felonies (Counts 2, 12, 13, 14, 30, 40, 57, 58, 62, 79, 80, 82, 122, 123, 135, 137, 142, 143, 144, and 167 through 174).

Petitioner Terry Hawkins was found guilty of 6 misdemeanors and 7 felonies. (Counts 10, 26, 76, 92, 121, 154, and 168 through 174).

Petitioner Donald Primmer was found guilty of 18 misdemeanors and 5 felonies. (Counts 73, 74, 95, 110, 112, 124, 125, 132, 133, 136, 138, 139, 140, 141, 145, 146, 147, 152, 168, 169, 171, 172, and 174).

On the remaining 111 Counts, Petitioners were found not guilty.

On June 15, 1979, Judge Kinneary sentenced Petitioners and issued and filed the Judgment and Order of Commitment.

On June 22, 1979, Petitioners filed a notice of Appeal with the Sixth Circuit Court of Appeals, challenging the validity of the convictions in the court below.

Briefs were submitted and oral argument was had.

On May 8, 1980, the Sixth Circuit Court of Appeals reversed the judgment of the district court for the reasons set forth in its opinion and remanded for a new trial.

The questions presented to this Court for review have been finally adjudicated and are not proper subjects of contention in the new trial. Said questions are, therefore, not premature but are ripe for adjudication by this Court.

B. Statement of the Facts Relevant to the Questions Presented for Review

At all times relevant herein, Petitioners Richard Seelig, Terry Hawkins and Donald Primmer were employed by Seelig Pharmacy, Inc. as pharmacists duly licensed in Ohio to practice pharmacy. [Transcript at Vol. II, p. 312; Vol. III, pps. 26, 65].

In April and May of 1978, the Federal Drug Enforcement Administration (DEA) conducted an investigative audit of the two (2) Seelig Pharmacies. [Transcript at Vol. I, p. 114]. Both are located in Columbus, Ohio; one, just north of the Ohio State University Campus on Summit Avenue, and the other located on the East side of Columbus on South Hamilton Road. [Transcript at Vol. I, p. 114]. The four (4) man audit team, headed by DEA compliance investigator Gerald Kopp spent ten (10) days at Seelig's Summit Avenue store and five (5) days at the Hamilton Road Pharmacy auditing records and inventory. [Transcript at Vol. I, p. 115].

Gerald Kopp testified that Petitioners cooperated fully with this investigation and admitted that the results of the inventory audit showed Seelig Pharmacy to have an excellent compliance record since the inventory was off only two-tenths of one percent (0.002%). [Transcript at Vol. I, pps. 225, 256, 258-259].

More than ten thousand (10,000) prescriptions of controlled substances were audited, of which Petitioners were indicted for nine (9) alleged illegal overfills of Schedule IV prescriptions in violation of 21 U.S.C. § 841(a)(1). [Counts 166-174 of Indictment; Transcript at Vol. II, p. 327; Vol. III, p. 81].

There were in excess of eighteen thousand (18,000) entries of sales of Schedule V substances audited consisting mainly of cough syrups with codeine, of which Petitioners were charged with one hundred sixty-five (165)

counts in the indictment for alleged illegal sales of more than four (4) ounces to the same purchaser within a 48-hour period, as prohibited by 21 C.F.R. § 1306.32, and purportedly in violation of 21 U.S.C. § 841(a)(1). [Counts 1-165 of Indictment; Transcript at Vol. III, p. 77].

Throughout the proceedings and trial below, Petitioners vigorously maintained their innocence. Each took the witness stand in their defense and denied knowingly and intentionally making any of the sales alleged to be criminally punishable. [Transcript at Vol. II, pps. 340-346, 349, 353, 355-356, 325; Vol. III, pps. 35-37, 44].

Furthermore, Petitioners have no prior convictions other than traffic offenses and each testified as to the various occasions they had reported to and cooperated with local law enforcement officials concerning forged or otherwise illegal narcotic prescriptions. [Transcript at Vol. II, pps. 323-324; Vol. III, pps. 31-32, 69-70].

Petitioners also testified that in the past they had relied upon law enforcement agencies to provide lists of overbuyers of controlled substances to effectively enforce the various drug laws. [Transcript at Vol. III, pps. 30, 71]. In particular, Petitioner Donald Primmer testified that he notified the Columbus Police about an increase in sales of Robitussin A/C (a Schedule V substance) and was advised not to worry about it. [Transcript at Vol. III, pps. 71, 75; Vol. II, p. 331].

Expert testimony was presented at trial which established that it is *not* the routine practice of pharmacists to check back into the exempt narcotics book to discover prior sales of Schedule V substances within a 48-hour period. [Transcript at Vol. II, pps. 193-194, 33; Vol. III, pps. 29, 75].

With regard to the refilling and/or renewal of prescriptions, as it relates to Counts 166-174 of the indictment,

expert testimony established that it was the routine practice of pharmacists and the Petitioners to renew a prescription upon the oral authorization of the issuing physician, often over the telephone, and to make an appropriate notation on the original prescription. [Transcript at Vol. II, pps. 195-197, 339, 342-343, 345; Vol. III, p. 44].

REASONS FOR GRANTING THE WRIT

Petitioners are three (3) Columbus, Ohio pharmacists who are being prosecuted for alleged violations of the Federal Controlled Substances Act, 21 U.S.C. § 841 (a) (1).

Their petition presents a question of first impression for the Court: whether or not the conduct of a licensed pharmacist that is technically in violation of an administrative regulation, specifically 21 C.F.R. §§ 1306.22, 1306.23 and 1306.32, promulgated by the United States Attorney General can be punished criminally under 21 U.S.C. § 841 (a) (1).

Petitioners also raise a unique evidentiary issue regarding the admissibility of a DEA official's opinion testimony on the controlling law that was vigorously contested at trial.

If the lower courts' interpretation of these legal principles is permitted to stand, Petitioners will be deprived of substantial rights heretofore protected by the decisions of this Court.

I. THE DISPENSING OF SCHEDULE IV AND V CONTROLLED SUBSTANCES BY A LICENSED PHARMACIST IN VIOLATION OF 21 C.F.R. §§ 1306.22, 1306.23, AND 1306.32 CANNOT BE CRIMINALLY PUNISHED UNDER 21 U.S.C. § 841(a)(1) OF THE FEDERAL CONTROLLED SUBSTANCES ACT.

The United States Attorney General's office promulgated 21 C.F.R. § 1306.32 which prohibits the sale of more than two (2) bottles of Robitussin A/C, a Schedule V non-prescription drug, over the counter, by licensed pharmacists to the same person in any given 48-hour period. In accordance with this administrative regulation, therefore, a pharmacist *is* authorized to sell more than two (2) bottles of Schedule V cough syrups containing codeine if 48 hours and 1 minute have expired. The Petitioners were convicted at trial of violating this arbitrary "48-hour rule" which ostensibly is also a violation of 21 U.S.C. § 841(a)(1).

Petitioners argued at trial and continue to defend against this prosecution, the very first of its kind, on the ground that professional conduct prohibited by this administrative regulation is not criminal under 21 U.S.C. § 841(a)(1).

Section 841(a)(1) is the criminal penalty section of the Federal Controlled Substances Act. The statute is drafted in the negative by outlawing any and all distribution or dispensing of controlled substances except as specifically authorized by the Controlled Substances Act.

Section 21 U.S.C. § 841(a)(1) reads as follows:

> *Except as authorized by this title*, it shall be unlawful for any person knowingly or intentionally—
>
> (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance. (Emphasis added).

Only "registrants", such as licensed pharmacists, are authorized to distribute or dispense controlled drugs under this federal law.

An example of the conduct authorized by the Controlled Substance Act is found in 21 U.S.C. § 822(b), which reads as follows:

> Persons registered by the Attorney General under this title to manufacture, distribute or dispense controlled substances are authorized to process, manufacture, distribute or dispense such substances (including any such activity in the conduct of research) *to the extent authorized by their registration and in conformity with the other provisions of this title.* (Emphasis added).

While 21 U.S.C. § 822(b) merely outlines the very basic requirements for distribution of controlled drugs, § 829 carefully defines specific standards of conduct registrants must follow relative to all five (5) schedules of controlled substances.

21 U.S.C. § 829 reads as follows:

> (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS § 301 et seq.] may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 USCS § 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 307 of this title [21 USCS § 827]. No prescription for a controlled substance in schedule II may be refilled.
>
> (b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user,

> no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act [21 USCS §301 et seq.] may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 USCS § 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.
>
> (c) *No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.*
>
> (d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 USCS § 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary to furnish to him all available data relevant thereto. (Emphasis added).

Section 829(c) plainly authorizes pharmacists to sell at retail, Robitussin A/C over the counter without a prescription so long as it is *for a medical purpose.*

On the other hand, 21 C.F.R. § 1306.32 attempts to define the term "*for a medical purpose*" in a purely bureaucratic fashion by providing that: (a) the sale is made only by a pharmacist; (b) not more than two (2) bottles be sold to the same person in any 48-hour period; (c) the purchaser is 18 years of age or older; (d) the pharmacist requires suitable identification from every purchaser; (e) the pharmacist shall maintain accurate bound records of every sale of over-the-counter Schedule V drugs including the purchaser's name and address, date, initials of seller, name and quantity of the product, all in accordance with 21 C.F.R. § 1304.04.

By unduly expanding the ordinary meaning of the term "medical purpose", the United States Attorney Gen-

eral's regulations on the distribution of Schedule V non-prescription drugs contravenes the express will of Congress as to what professional conduct can be punished criminally. Rather than intend criminal sanctions for the sale of Schedule V drugs, Congress specifically provided for civil enforcement and sanctions under 21 U.S.C. § 842. See *U.S.* v. *Barbacoff*, 416 F.Supp. 606 (D.C. 1976); *U.S.* v. *Williams*, 416 F.Supp. 611 (D.C. 1976).

In *Barbacoff, supra*, the facts were far more egregious than in the case at bar, yet, the defendants were not indicted under 21 U.S.C. § 841(a)(1), but were issued a cease and desist order under 21 U.S.C. § 842. The defendants in *Barbacoff* had filled Schedule II prescription drugs in violation of the controlling statutes and regulations, yet were only assessed civil penalties.

In *Williams, supra*, a pharmacist who filled forged and photocopied prescriptions and who failed to maintain complete and accurate records with respect to receipt and distribution of certain drugs, and who filled Schedule II prescription drugs when he knew or should have known that many of them had not been issued in the course of legitimate medical practice was assessed only civil liability.

The case of *U.S.* v. *Seelig, et al.* is the very first prosecution for violating the so-called 48-hour rule promulgated by the United States Attorney General. The Court below incorrectly held that:

> [t]he Statute (§ 841(a)(1)) does expressly, albeit in a convoluted fashion, provide that a violation of the promulgated rules constitutes an unlawful act under the Controlled Substances Act." p. 5.

The Court below reasoned that because the Attorney General is authorized under § 841 and § 871 to promulgate rules and regulations "that he deems necessary for the efficient execution of his functions," and to register

all persons licensed to handle controlled substances, then all of the resulting rules and regulations constitute criminal standards of behavior punishable under § 841(a)(1).

The Sixth Circuit, in the case at bar, relied exclusively on the rationale in *U.S.* v. *Green*, 511 F.2d 1062 (7th Cir. 1975) cert. den. 423 U.S. 1031. *Green* dealt with a different regulation passed by the Attorney General, 21 C.F.R. § 1306.04(a), concerning prescriptions and the natural professional standards requiring pharmacists to fill only those prescriptions that are issued by the physician in the ordinary course of professional treatment. Section 1306.04(a), as the court in *Green* correctly held, does not expand the natural meaning of the statutory authorization for distributing prescription drugs found in § 829(a) and (b). Sections 829(a) and (b) expressly mandate the dispensing of prescriptions, written or oral, by pharmacists in conformity with § 503(j) of the Federal Food, Drug and Cosmetic Act. The regulation in *Green, supra*, merely supplements the statutory language by naturally requiring professional conduct of pharmacists. Likewise, § 829 incorporates the statutory terms dispensing and practitioner as defined in § 802(10) and (20). Once these critical terms are defined and applied, it plainly appears that 21 C.F.R. § 1306.04 mimics and merely supplements the controlling statute.

Thus, the court in *Green* properly allowed the criminal prosecution of two (2) physicians and a pharmacist for having dispensed controlled substances outside the scope of their professional practice.

The case of *U.S.* v. *Seelig*, however, differs drastically from a criminal prosecution under § 1306.04. Petitioners were convicted on Counts 1-165 of the indictment on the basis that their conduct allegedly violated 21 C.F.R. § 1306.32(b). This regulation does not attempt to define or supplement the statutory concept of "medical purpose" as set forth in 21 U.S.C. § 829(c). Rather, it arbitrarily

expands and bureaucratically annoints a 48-hour rule that is totally unrelated to the notion of medical purpose. The question of what is a "medical purpose" relates to matters of professional judgment and legitimate treatment instead of the number of bottles of cough syrup sold over the counter.

The 48-hour rule establishes a bureaucratic presumption that all purchases of a Schedule V substance by the same retail purchaser within a 48-hour period are for non-medical purposes. Such a blanket prohibition invades the judgment of the practitioner and contradicts the intent of Congress. Had Congress intended to criminally sanction the sale of Schedule V drugs, it would have designated them as prescription drugs. See House Report No. 91-1444, 91st Cong., 2d Session, 1970 U.S. Code Cong. & Admin. News 4566.*

Other statutes, governing areas of conduct and social interaction that are as complex as the regulation of controlled substances, have been phrased in precise terms when Congress intended to delegate the function of defining criminal acts to some administrative body. This court has long since required Congress to expressly state that the violation of administrative rules are criminally punishable. *U.S.* v. *Grimaud*, 220 U.S. 506 (1911).

For example, § 10 of the Securities and Exchange Act of 1934, 15 U.S.C. § 78j provides as follows:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—
>
> (a) To effect a short sale, or to use or employ a stop-loss order in connection with the pur-

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* It must be noted that nowhere in the legislative history is it mentioned that conduct falling outside the scope of the Attorney General's regulations will be criminally punished.

> chase or sale, of any security registered on a national securities exchange, *in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.*
>
> (b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance *in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.*

See, also, 15 U.S.C. §§ 78n; Cf. 29 U.S.C. §§ 207(g)(3), 207(m)(1), and 211d, which are additional examples of instances where Congress enacted statutory language expressly providing that violations of the regulations promulgated under the authority of the statute would be violations of the statute.

The absence of such precision with respect to 21 U.S.C. § 829(c) manifests Congress's intent to limit control of the dispensing of Schedule V substances to the requirement that the specified substances be dispensed only for a medical purpose. Had it intended more stringent regulation, it should have provided so expressly.

In addition to the foregoing illustrations 21 C.F.R. § 1306.32 contains many other directives that do not define "medical purpose." Instead, they impermissibly expand the scope of 21 U.S.C. § 841(a)(1).

If the lower court interpretation of 21 C.F.R. § 1306.32 is allowed to stand, violation of any of the directives set forth in the aforementioned regulation will constitute a violation of 21 U.S.C. § 841(a)(1). Accordingly, such omissions as failure to demand identification from a potential purchaser will result in criminal punishment.

Additionally, the failure of a pharmacist to maintain a bound record book which contains the name and quantity of the controlled substance purchased, the purchase date, and the signature or initialling of the dispensing pharmacist could well result in criminal punishment under 21 U.S.C. § 841(a)(1). Thus, pharmacists must agonize each time a sale of cough syrup is made for fear of having failed to properly initial the record book or having erroneously recorded the street address of the purchaser. Under the very worst scenario, a pharmacist could be prosecuted if he used a loose-leaf record book instead of a bound record volume. The possibilities for prosecution for failure to comply exactly with the directives are endless. Those examples cited, however, adequately indicate the ridiculous posture of 21 C.F.R. § 1306.32.

For many of the same reasons, 21 C.F.R. §§ 1306.22 and 1306.23 impermissibly expand the scope of 21 U.S.C. § 841(a)(1). By attempting ostensibly to define an exception, the Attorney General's regulations, 21 C.F.R. § 1306.22 and 1306.23, limit what was intended by Congress as legally permissible conduct. The result is that now a larger category of conduct is susceptible to criminal punishment.

Following much the same analysis employed with respect to 21 C.F.R. § 1306.32, it must be initially noted that 21 U.S.C. § 841(a)(1) provides for exceptions. Accordingly, 21 U.S.C. § 822(b) permits registrants to dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions of this title." Focusing more narrowly, a careful reading of § 829(b) discloses that "prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription *unless renewed by the practitioner.*" The underlined portion of the last sentence implies that if six months have expired from the original issuing date

of the prescription or if five refills have been extended on the original prescription, the practitioner must *renew* the original prescription before additional quantities of the controlled substance are dispensed. It appears, however, that 21 C.F.R. § 1306.22 does not follow the statutory guidelines but is instead more restrictive.

Initially, it must be noted that the first sentence of 21 C.F.R. § 1306.22(a) provides that "No prescription for a controlled substance listed in schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times." Up to this point, the regulation merely mimics the statutory language of 21 U.S.C. § 829(b); (last sentence). Shortly thereafter, subsection (a) of 21 C.F.R. § 1306.22 delineates the manner in which additional quantities of the controlled substance which is the subject of the original prescription may be dispensed when the original prescription has become unenforceable because of the six-month or five-refill limitation previously mentioned. Specifically subsection (a) states that:

> Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in § 1306.21 which shall be a new and separate prescription.

Proceeding further, and carefully comparing the language of 21 U.S.C. § 829(b) with the language of 21 C.F.R. § 1306.22(a), it becomes readily apparent that while § 829(b) merely requires a practitioner to "renew" a prescription, 21 C.F.R. § 1306.22(a) requires the practitioner to issue a "new" prescription. Unless a court can construe the words "new" and "renew" as having the same meaning, the inevitable conclusion to be reached is that 21 C.F.R. § 1306.22(a) unduly restricts what Congress otherwise intended to be permissible conduct.

The sole act forming the basis for the prosecution below was the alleged failure of Petitioners to reduce an oral renewal prescription to writing on a separate piece of paper rather than noting the same on the reverse side of the original prescription.

Congress never intended such an absurd result. Congress should have expressly provided, as it did with the securities laws hereinbefore mentioned, that violations of the regulations would constitute a violation of § 841 (a) (1). Nowhere in the statute or in the legislative history, is such an intent manifested.

The foregoing analysis is equally applicable to 21 C.F.R. § 1306.23. Initially, it must be observed that subsection (a) of 21 C.F.R. § 1306.23 refers one back to 21 C.F.R. § 1306.22(a), which, as has been stated previously, is replete with defects. In addition, subsection (c) provides that "no dispensing occurs after 6 months after the date on which the prescription was issued." Because this subsection contains no provision for renewal, it limits the scope of permissible conduct more severely than 21 U.S.C. § 829(b) and, correspondingly, expands the scope of 21 U.S.C. § 841(a)(1). Such a result may not be condoned.

In promulgating these regulations, the Attorney General has violated the doctrine of separation of powers. Because of the manner in which the statutory scheme of the Controlled Substances Act functions, violations of the regulations promulgated by the Attorney General allegedly constitute violations of 21 U.S.C. § 841(a)(1). Based upon the prosecution below, the operation of the regulations can only be characterized as having the force and effect of penal laws. If the regulations do no more than mimic the statutes, as does 21 C.F.R. § 1306.04, no harm is done, for in that case, the regulation is consistent with the statute. However, in the case at bar, the regulations exceed the scope of the statute and operate not as a

exception but as a penal law. It was to prevent such an occurrence that our forefathers incorporated the doctrine of separation of powers into the Constitution. To preserve this hallowed legal principle, 21 C.F.R. §§ 1306.22, 1306.23 and 1306.32 should be held to be not only impermissible expansions of 21 U.S.C. § 841(a)(1), but constitutionally defective as well.

Congress has not provided criminal penalties for acts contrary to such regulations adopted by the United States Attorney General. See: 21 U.S.C. § 821. The operative language of 21 U.S.C. § 841 clearly prohibits illegitimate drug trafficking. It is noteworthy that this Court recently characterized 21 U.S.C. § 841 as the federal design for prosecuting the "offense of acting as a drug 'pusher' ". *United States* v. *Moore*, 423 U.S. 122 (1975).

The foregoing analysis clearly indicates that the Attorney General has exceeded the scope of the powers granted to him. The regulation in question has expanded 21 U.S.C. § 841(a)(1). Petitioners submit, on the basis of the reasoning set forth in *Grimaud*, that such action is impermissible. Accordingly, the prosecution below cannot be upheld on the basis that Petitioners violated 21 C.F.R. §§ 1306.22, 1306.23 and 1306.32.

II. THE TESTIMONY OF D.E.A. COMPLIANCE INVESTIGATOR, GERALD KOPP, VIOLATED RULES 403, 702, AND 704, FEDERAL RULES OF EVIDENCE, INSOFAR AS IT RELATED TO "THE LAW" CONTROLLING THE PROSECUTION OF THIS CASE.

It is fundamental to Anglo-American Jurisprudence that it is within the sole province of the Trial Court to provide the Jury with the controlling law. Likewise, it is an equally universal maxim that *no* witness can testify as to the law. 31 Am.Jur.2d, *Expert and Opinion Evidence*, § 69. Yet, this trial court's decisions, as affirmed by the Court of Appeals, repeatedly and erroneously al-

lowed chief prosecution witness Gerald Kopp to testify as to his personal opinion of the Federal Law, Petitioners have been convicted of violating.

Petitioners direct the Court's attention to the following direct testimony by Gerald Kopp adduced over counsel's vigorous objections.

> Q. What basically did you find by looking through those books?
>
> MR. MATAN: Objection again, Your Honor.
>
> THE COURT: Overruled. Go ahead.
>
> A. We found a pattern of people continuously purchasing Robitussin A/C, or one of the exempt controlled substances, and we found several instances were making purchases within the 48-hour time limit.
>
> Q. When you saw such a purchase, did you make any notation?
>
> A. Yes.
>
> THE COURT: This is a purchase within a 48-hour period?
>
> Q. That's correct. What did you do?
>
> A. I circled it and I numbered it. The first I numbered 1 and continued through the books in that manner.
>
> Q. With regard to the time period, why did you pick the 48-hour time period to single out certain purchases?
>
> A. Because under the Controlled Substances Act they can only purchase these exempt preparations, one four-ounce bottle within 48 hours, a 48-hour time period.
>
> BY THE COURT:

Q. You say they can only purchase one four-ounce bottle within a 48-hour time period?

A. That's correct, sir.

Q. Don't you really mean that when a person goes into a drugstore and buys a Schedule V controlled substance, specifically Robitussin, that he cannot make another purchase of that controlled substances until 48 hours expires from his first purchase?

A. Yes, sir.

Q. That's what you mean; isn't it?

A. Yes, sir.

Q. But not within 48 hours?

A. Exactly.

MR. MATAN: Your Honor, we would object and ask that be stricken on the basis this is a matter of law for the Court to instruct the jury.

THE COURT: Overruled.

BY MR. HUNT:

Q. Based upon your experience with the way the drug law operates, are pharmacists under a duty to insure that such a violating purchase is not made within that time period?

MR. MATAN: I am going to object. That is for the Court to determine and the jury, it is an ultimate question of law and fact.

THE COURT: Overruled.

A. Yes, it is in the regulations which govern the sales of the controlled substance that it is the pharmacist's duty to make sure that he does not sell it in 48 hours.

[Transcript at Vol. I, pps. 124-126].

Rather than allow trial counsel for Petitioners to interject specific objections for the record, the Court below

granted a continuing objection for any and all reasons relative to Gerald Kopp *and at the same time* overruled each and every one of them. [Transcript at Vol. I, p. 135].

The government then proceeded to pose leading questions to Kopp at the beginning of their presentation of Exhibits 1 through 165, to which he answered nine (9) consecutive times that the particular exhibits show sales "*in violation of the 48-hour rule.*" [Transcript at Vol. I, pps. 125-141]. Finally, the Trial Court instructed Kopp to delete any reference to "violation" yet encouraged him to continue referring to the 48-hour time period. [Transcript at Vol. I, p. 141]. After three (3) more consecutive references to this 48-hour time frame, the Court below temporarily stopped such blatantly erroneous testimony. [Transcript at Vol. I, p. 142]. But by that time, the prejudicial damage was beyond repair.

Thereafter, on re-direct examination, despite its earlier admonition, the Trial Court compounded its error by allowing and participating in the clearly improper and highly inflammatory questioning of Kopp on the law. Because this line of questioning was so prejudicial to the substantial right of Petitioners and equally critical to this petition for writ of certiorari, the aforesaid testimony of Kopp on redirect examination is reproduced below:

BY MR. HUNT:

Q. Mr. Kopp, I want to direct your attention to the requirements as you understand them for keeping records that would enable the pharmacist to refrain from making sales within the 48-hour time period.

Are you familiar with that regulation?

A. Yes.

MR. MATAN: Object.

THE COURT: Ladies and gentlemen of the jury, the Court has attempted to stop that hammering.

Read the question back to me.

(Question read.)

THE COURT: Do you object to that?

MR. MATAN: Yes.

THE COURT: Overruled.

MR. MATAN: Does the Court wish any reasons?

THE COURT: No.

Is he familiar with the regulation, and he said he is familiar with the regulation.

A. Yes, sir.

Q. Does the regulation prohibit the sale within 48 hours of cough syrup containing codeine?

MR. MATAN: Object for several reasons, if the Court wishes to hear them.

THE COURT: Overruled.

A. Yes, it does.

Q. Can you tell in you own words what the regulation requires of a pharmacist?

MR. MATAN: Object.

THE COURT: Overruled.

Q. Go ahead and answer the question: What is he required to do pursuant to the regulation?

MR. MATAN: Object.

THE COURT: Overruled.

[Transcript at Vol. I, pps. 304-306].

In addition to the foregoing prejudicial errors relative to Counts 1 through 165, the Court below further erred with respect to the felony charges of Counts 166 through 174 for alleged prescription overfills of Schedule IV sub-

stances by, once again, allowing and practically encouraging Kopp to testify as to *his own* interpretation of the controlling law.

In that regard, please consider the following testimony given by Gerald Kopp:

> [MR. HUNT]
>
> Q. Based upon your experience and your knowledge of the drug field, customarily what does a pharmacy or pharmacist do when he fills a prescription the first time?
>
> A. He is required—
>
> MR. MATAN: Objection, Your Honor.
>
> THE COURT: Overruled.
>
> A. He is required by law to indicated the date the prescription was filled and his initials, and if the quantity is any different that what was—then the prescription was written for. He is required to list the quantity dispensed.
>
> MR. MATAN: Object and ask that be stricken.
>
> THE COURT: Come up, gentlemen.
>
> (Discussion off the record.)
>
> THE COURT: The objection to the last question and answer is overruled.
>
> [Transcript at Vol. I, pps. 228-229].
>
> [MR. MATAN]
>
> Q. From your understanding and your experience, isn't it true that a physician may authorize an oral renewal of a prescription?
>
> A. Yes, as long as he does not exceed the five refills that are on the prescription.
>
> Q. Are you sure that's the way you want to answer that?
>
> A. Yes, a prescription is only valid for five refills, and that's all.

BY THE COURT:

Q. I would like to ask the question to straighten my thinking: A physician offers a prescription for Darvon?

A. Yes, sir.

Q. Let's say the amount is 50 units, and he authorizes let's say, three refills under that prescription?

A. Yes, sir.

Q. In order to refill the prescription after it is filled the first time, does the druggist need anything except the original prescription, that is does he need either the oral or written authorization of the physician in order to fill it the second and third time?

A. No, sir.

[Transcript at Vol. I, pps. 271-272].

Here the Trial Court dignifies and adds authority to Kopp's own interpretation of the law by asking his advice on "the law"—something that the Judge is supposed to instruct the jury on. Petitioner's trial counsel in attempting to obtain some rebuttal to Kopp's interpretation of the law is again silenced by Judge Kinneary.

BY MR. MATAN:

Q. I would like some information like the Judge: Would this be correct that such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner; is that correct?

A. Yes.

Q. So that if it is renewed by the practitioner, it can be more than five times?

A. No, because the pharmacist is required to—If it is a drug that can be called in over the telephone,

the pharmacist is required to make a new prescription for that additional authorization.

Q. It doesn't say that in the law; does it?

MR. HUNT: Objection.

THE COURT: Sustained.

[Transcript at Vol. I, pps. 272-273].

Once again, prejudice naturally flows from the testimony since the controlling law as to prescription refills and renewal under Counts 166 to 174 was and remains in dispute. Clearly, those parts of the law testified to by Kopp and those parts that were instructions by the Court would be indistinguishable to the jury.

If this Court were to condone Trial Judges allowing law enforcement personnel to render opinion testimony on the controlling law, defense counsel would be forced to counter with the truly expert testimony of attorneys to enlighten juries with their professional opinions and interpretations of any statute at issue. Such a practice would not only disserve the administration of justice greatly, but it would seriously undermine the heretofore exclusive province of the Trial Court. For example, *United States* v. *Sink*, 355 F.Supp. 1067 (E.D. Pa. 1973), affirmed, 485 F.2d 683 (1973), involved the prosecution of a union president for accepting illegal payments from employers and the District Court ruled inadmissible opinions by representatives of the employer, including a lawyer, as to what conduct constituted a violation of the Labor Management Relations Act.

Such testimony is patently beyond the scope of Rules 702 and 704, Federal Rules of Evidence. Testimony of this nature does not go to the ultimate issues of fact, but rather concerns the so-called expert interpretation of Federal Criminal Law.

In *Marx & Co.* v. *Diners' Club, Inc.*, 550 F.2d 505 (2nd Cir. 1977) cert. den. 434 U.S. 861, the Second Circuit

Court of Appeals held that the trial court erred when, in an action for an alleged breach of an agreement to register stock received by the plaintiffs in a transaction in which defendants acquired assets of the plaintiffs' corporation in exchange for corporate stock, it permitted an expert witness called by plaintiffs to give his opinion as to the legal obligations of the parties under the contract; even though the witness, a lawyer, was qualified as an expert in securities regulation and, therefore, competent to explain step-by-step practices ordinarily followed by lawyers and corporations in shepherding registration statements through the Securities Exchange Commission. *See, also, Eastern Associated Coal* v. *Aetna Casualty & Surety Co.*, 475 F.Supp. 586 (1979).

Additionally, Rule 403, Federal Rules of Evidence permits the trial judge to exclude relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence. Although the trial judge is to be granted latitude in exercising the judicial discretion accorded him under this rule, admission of the testimony of Gerald Kopp unfairly prejudiced Petitioners' rights, confused the issues, and mislead the jury by forcing them to distinguish between the testimony and the Court's instructions. The Trial Court below abused its discretion in allowing this testimony.

Finally, and perhaps most importantly, admission of opinion testimony relating to the law controlling the prosecution of a criminal case deprives an accused of his right to have the jury instructions issued by the court and accordingly emaciates the concepts of procedural due process heretofore vigorously protected by this Court. The very essence of our system of jurisprudence contemplates a trier of fact and interpreter of the law. While

the court may exercise both functions simultaneously, the jury may only try the facts. To allow testimony like that of Gerald Kopp to be admitted into evidence serves to slowly erode this time honored division of authority.

On the basis of the foregoing analysis, Petitioners submit that Gerald Kopp's testimony violated Rules 403, 702 and 704, Federal Rules of Evidence depriving Petitioners of procedural due process and should have been accordingly excluded.

CONCLUSION

The foregoing reasons for granting a writ of certiorari demonstrate the importance of the above discussed questions to a final disposition of this case. For these reasons, a writ of certiorari should issue to review the judgment of the Sixth Circuit Court of Appeals.

Respectfully submitted,

DANA G. RINEHART
MATAN, RINEHART & SMITH
261 South Front Street
Columbus, Ohio 43215
(614) 228-2678

Attorney for Petitioners

Dated: July 7, 1980

APPENDIX

APPENDIX

A. Statutes and Regulations

21 U.S.C. § 801:

§ 801. Findings and declarations

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

21 U.S.C. § 802(10) (Definitions):

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

21 U.S.C. § 802(20) (Definitions):

(20) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered,

or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

21 U.S.C. § 821:

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

21 U.S.C. § 822(b):

§ 822. Persons required to register

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

21 U.S.C. § 829:

§ 829. Prescriptions

(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS § 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such

drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 USCS § 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 307 of this title [21 USCS § 827]. No prescription for a controlled substance in schedule II may be refilled.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS § 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 USCS § 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 USCS § 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

21 U.S.C. § 841(a)(1):

§ 841. Prohibited acts A—Penalties

(a) Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; . . .

21 U.S.C. § 871:

§ 871. Procedures

(a) The Attorney General may delegate any of his functions under this title to any officer or employee of the Department of Justice.

(b) The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title.

(c) The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

15 U.S.C. § 78j:

§ 78j. Manipulative and deceptive devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—

(a) To effect a short sale, or to use or employ any stop-loss order in connection with the purchase or sale, of any security registered on a national securities exchange, in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive de-

vice or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78n:

§ 78n. Proxies; tender offers

(a) It shall be unlawful for any person, by the use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 USCS § 78l].

(b) It shall be unlawful for any member of a national securities exchange, or any broker or dealer registered under this title [15 USCS §§ 78a et seq.], in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors, to give, or to refrain from giving a proxy, consent, or authorization in respect of any security registered pursuant to section 12 of this title [15 USCS § 78*l*] and carried for the account of a customer . . .

29 U.S.C. § 207(g)(3)

(g) No employer shall be deemed to have violated subsection (a) by employing any employee for a workweek in excess of the maximum workweek applicable to such employee under such subsection if, pursuant to an agreement or understanding arrived

at between the employer and the employee before performance of the work, the amount paid to the employee for the number of hours worked by him in such workweek in excess of the maximum workweek applicable to such employee under such subsection— . . .

(3) is computed at a rate not less than one and one-half times the rate established by such agreement or understanding as the basic rate to be used in computing overtime compensation thereunder:

Provided, That the rate so established shall be authorized by regulation by the Administrator as being substantially equivalent to the average hourly earnings of the employee, exclusive of overtime premiums, in the particular work over a representative period of time; and if (i) the employee's average hourly earnings for the workweek exclusive of payments described in paragraphs (1) through (7) of subsection (e) are not less than the minimum hourly rate required by applicable law, and (ii) extra overtime compensation is properly computed and paid on other forms of additional pay required to be included in computing the regular rate.

29 U.S.C. § 207(m)(1):

(m) For a period or periods of not more than fourteen workweeks in the aggregate in any calendar year, any employer may employ any employee for a workweek in excess of that specified in subsection (a) without paying the compensation for overtime employment prescribed in such subsection, if such employee—

(1) is employed by such employer—

(A) to provide services (including stripping and grading) necessary and inciden-

tal to the sale at auction of green leaf tobacco of type 11, 12, 13, 14, 21, 22, 23, 24, 31, 35, 36, or 37 (as such types are defined by the Secretary of Agriculture [see 30 CFR § 30.1 et seq.]), or in auction sale, buying, handling, stemming, redrying, packing, and storing of such tobacco,

29 U.S.C. § 208:

§ 208. Wage orders in Puerto Rico and the Virgin Islands

(a) The policy of this Act [29 USCS §§ 201 et seq.] with respect to industries or enterprises in Puerto Rico and the Virgin Islands engaged in commerce or in the production of goods for commerce is to reach as rapidly as is economically feasible without substantially curtailing employment the objective of the minimum wage rate which would apply in each such industry under paragraph (1) or (5) of section 6(a) [29 USCS § 206(a)(1) or (5)] but for section 6(c) [29 USCS § 206(c)]. The Secretary shall, from time to time, convene an industry committee or committees, appointed pursuant to section 5, and any such industry committee—

(1) shall, from time to time, recommend the minimum wage rates to be paid by employers who are in Puerto Rico, in the Virgin Islands, or in both places and who but for section 6(c) [29 USCS § 206(c)] would be subject to the minimum wage requirements of section 6(a)(1) [29 USCS § 206(a)(1)], and

(2) may, from time to time, recommend increases in the incremental increases authorized by section 6(c)(2) [29 USCS § 206(c)(2)].

The Administrator shall from time to time convene an industry committee or committees, appointed pur-

suant to section 5 [29 USCS § 205] and any such industry committee shall from time to time recommend the minimum rate or rates of wages to be paid under section 6 [29 USCS § 206] by employers in Puerto Rico or the Virgin Islands, or in Puerto Rico and the Virgin Islands, engaged in commerce or in the production of goods for commerce or in any enterprise engaged in commerce or in the production of goods for commerce in any such industry or classifications therein. Minimum rates of wages established in accordance with this section which are not equal to the otherwise applicable minimum wage rate in effect under paragraph (1) or (5) of section 6(a) [29 USCS § 206(a)(1) or (5)] shall be reviewed by such a Committee once during each biennial period, beginning with the biennial period commencing July 1, 1958, except that the Secretary, in his discretion, may order an additional review during any such biennial period.

(b) Upon the convening of any such industry committee, the Administrator shall refer to it the question of the minimum wage rate or rates to be fixed for such industry. The industry committee shall investigate conditions in the industry and the committee, or any authorized subcommittee thereof, shall after due notice hear such witnesses and receive such evidence as may be necessary or appropriate to enable the committee to perform its duties and functions under this Act [29 USCS §§ 201-216, 217-219, 557]. The committee shall recommend to the Administrator the highest minimum wage rates for the industry which it determines, having due regard to economic and competitive conditions, will not substantially curtail employment in the industry, and will not give any industry in Puerto Rico or in the Virgin Islands a competitive advantage over any

industry in the United States outside of Puerto Rico and the Virgin Islands; except that the committee shall recommend to the Secretary the minimum wage rate prescribed in section 6(a) or 6(b) [29 USCS § 206(a) or (b)], which would be applicable but for section 6(c) [29 USCS § 206(c)], unless there is substantial documentary evidence, including pertinent unabridged profit and loss statements and balance sheets for a representative period of years or in the case of employees of public agencies other appropriate information, in the record which establishes that the industry, or a predominant portion thereof, is unable to pay that wage.

(c) The industry committee shall recommend such reasonable classifications within any industry as it determines to be necessary for the purposes of fixing for each classification within such industry the highest minimum wage rate (not in excess of that in effect under paragraph (1) or (5) of section 6(a) [29 USCS § 206(a)(1) or (5)] (as the case may be)) which (1) will not substantially curtail employment in such classification and (2) will not give a competitive advantage to any group in the industry, and shall recommend for each classification in the industry the highest minimum wage rate which the committee determines will not substantially curtail employment in such classification. In determining whether such classifications should be made in any industry, in making such classifications, and in determining the minimum wage rates for such classifications, no classifications shall be made, and no minimum wage rate shall be fixed, solely on a regional basis, but the industry committee shall consider among other relevant factors the following:

(1) competitive conditions as affected by transportation, living, and production costs;

(2) the wages established for work of like or comparable character by collective labor agreements negotiated between employers and employees by representatives of their own choosing; and

(3) the wages paid for work of like or comparable character by employers who voluntarily maintain minimum wage standards in the industry.

No classification shall be made under this section on the basis of age or sex.

(d) The industry committee shall file with the Secretary a report containing its findings of fact and recommendations with respect to the matters referred to it. Upon the filing of such report, the Secretary shall publish such recommendations in the Federal Register and shall provide by order that the recommendations contained in such report shall take effect upon expiration of 15 days after the date of such publication.

(e) Orders issued under this section shall define the industries and classifications therein to which they are to apply, and shall contain such terms and conditions as the Administrator finds necessary to carry out the purposes of such orders, to prevent the circumvention or evasion thereof, and to safeguard the minimum wage rates established therein.

(f) Due notice of any hearing provided for in this section shall be given by publication in the Federal Register and by such other means as the Administrator deems reasonably calculated to give general notice to interested persons.

29 U.S.C. § 211(d):

(d) The Administrator is authorized to make such regulations and orders regulating, restricting, or

prohibiting industrial homework as are necessary or appropriate to prevent the circumvention or evasion of and to safeguard the minimum wage rate prescribed in this Act [29 USCS §§ 201-216, 217-219, 557], and all existing regulations or orders of the Administrator relating to industrial homework are hereby continued in full force and effect.

21 C.F.R. § 1306.04(a):

§ 1306.04 Purpose of issue of prescription

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility of the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in the legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.32:

§ 1306.32 Dispensing without prescription

A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in § 1306.02(d), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

§ 1306.22 Refilling of prescriptions

(a) No prescription for a controlled substance listed in schedule II or IV shall be filled or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription (or on another appropriate uniformly maintained, readily retrievable record, such as medication records, which indicates by the number of the prescription the following information: The name and dosage form of the controlled substance, the date of each refilling, the quantity dispensed, the identity or initials of the dispensing pharmacist in each refilling, and the total number of refills for that prescription), initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription he shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in § 1306.21 which shall be a new and separate prescription.

(b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This

shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated

is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and

the number of the original prescription order. In any computerized system order. In any computerized system employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Compliance Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills on Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for one-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

(d) Any registrant who intends to use a system provided by paragraph (b) of this section must first apply for a Permit to Maintain Central Records as required by § 1304.04(a).

§ 1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

Rule 403, Federal Rules of Evidence:

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 702, Federal Rules of Evidence:

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 704, Federal Rules of Evidence:

Rule 704. Opinion on Ultimate Issue

Testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

B. Opinion of the Court of Appeals for the Sixth Circuit of May 8, 1980

Nos. 79-5232, 79-5233, 79-5234

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,
v.

RICHARD SEELIG, TERRY HAWKINS,
and DONALD PRIMMER,
Defendant-Appellants.

Appeal from the United States District Court
for the Southern District of Ohio,
Eastern Division

Decided and Filed May 8, 1980

Before: KENNEDY and JONES, Circuit Judges, and PHILLIPS, Senior Circuit Judge.

KENNEDY, Circuit Judge. Appellants are three pharmacists who appeal their misdemeanor convictions for distributing codeine-based cough medicines and felony

convictions for distributing Dextropropoxyphene (brand name Darvon) and Diazepam (brand name Valium) in violation of the Controlled Substances Act, 21 U.S.C. § 841(a)(1). Appellants claim the indictments fail to state a crime with respect to the misdemeanor counts and fail to allege facts which would constitute a crime with respect to the felony counts and that the court should have granted their motion for acquittal as there was no evidence of intent. They claim certain evidence was erroneously admitted and other evidence erroneously rejected.

I. Sufficiency of the Indictments

Appellants are pharmacists duly licensed to practice pharmacy in Ohio. All are employed by Selig Pharmacy, Inc., which has two stores in Columbus, Ohio. The indictment consists of 174 counts, each for a separate distribution of a controlled substance. Count One charged Richard Seelig with knowingly or intentionally and unlawfully distributing a schedule V controlled substance by distributing without a prescription more than four ounces of Robitussin A/C within a 48-hour period, as prohibited by 21 C.F.R. § 1306.32, in violation of 21 U.S.C. § 841(a)(1). Counts 2-165 list other similar sales of Robitussin A/C, Terpin Hydrate Codeine, or Histadyl E/C, schedule V controlled substances. The remaining counts charge the appellants with knowingly or intentionally and unlawfully distributing schedule IV controlled substances by unlawfully refilling prescriptions for Diazepam (brand name Valium) or Dextropropoxyphene (brand name Darvon).

Appellants raise two challenges to the indictment. First, that counts 1-165 do not charge appellants with a crime but with only a violation of a regulation. Second, that counts 166-174 do not allege sufficient facts to constitute a crime as there is no allegation that the sub-

stances were not distributed within the usual course of professional practice.

COUNTS 1-165

Appellants argue that the sale of more than four ounces of Robitussin (or other schedule V substance) within 48 hours to one person, while it violates the regulation, does not violate the Controlled Substances Act, that the Act does not make violations of the regulations criminal, and that the Attorney General, who promulgates the regulations, does not have the authority to expand the criminal liability determined by Congress in the statute. According to appellants, the statute must explicitly state that a violation of the regulations constitutes an offense. Appellants rely upon *United States* v. *Grimaud*, 220 U.S. 506 (1911), which upheld a criminal conviction for using the Sierra Forest Preserve for sheep grazing without a permit as required by regulations, where the statute authorizing the promulgation of the regulations explicitly stated that anyone who violated the statute or the rules and regulations thereunder would be subject to criminal penalties. The Supreme Court distinguished a previous case, *United States* v. *Eaton*, 144 U.S. 677 (1892), which involved a violation of regulations requiring certain books to be kept of oleomargarine sales. In *Eaton*, the statute required one kind of book be kept, but imposed no penalty for failing to do so. The Commissioner went further and required another kind of book. To hold someone criminally liable for violating the regulation in *Eaton*, said the *Grimaud* Court, "manifestly was putting the regulations above the statute." 220 U.S. at 519. Thus, a person may be held criminally liable for the violation of a regulation, but only if the statute which authorizes the promulgation of the regulations makes the violation of the regulations a crime.

The Controlled Substances Act defines what drugs are subject to control of their manufacture and distribution and lists these drugs in schedules, with different provisions pertaining to each schedule. *See* 21 U.S.C. §§ 811, 812, 823, 829. Section 841(a)(1) provides:

> (a) Except as authorized by this subchapter [The Controlled Substances Act], it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; . . .

Appellants claim that they need only comply with other statutory provisions to fit within the exception stated in § 841(a)(1) and are not, as the government argues, required to comply with the regulations promulgated under the subchapter in order to distribute "as authorized by this subchapter".

Section 829(c) provides:

> No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

Appellants claim this section authorizes them to distribute or dispense schedule V drugs such as Robitussin for medical purposes regardless of whether more than four ounces of the drug is given to one person within a 48-hour period, despite the prohibition of 21 C.F.R. § 1306.32. Appellants' argument rests on a negative implication from § 829(c). Were there no other provisions which explicitly stated when the distribution or dispensing of schedule V drugs were authorized, this Court might accept appellants' argument. However, § 822(b) does provide the express authorization. It states:

> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dis-

> pense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

The combination of § 829(c) and § 822(b) thus requires a person to dispense or distribute a schedule V drug for a medical purpose and to be within the authority of their registration as determined by the Attorney General. Section 822(a) requires every person who distributes or dispenses controlled substances to register with the Attorney General. Section 821 authorizes the Attorney General to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. Section 871(b) authorizes the Attorney General to promulgate and enforce rules, regulations, and procedures that he deems necessary for the efficient execution of his functions.

Although Congress was not as clear in this statute as in the one involved in *Grimaud*, this Court is satisfied that the statute does expressly, albeit in a convoluted fashion, provide that a violation of the promulgated rules constitutes an unlawful act under the Controlled Substances Act. Thus, counts 1-165 do charge crimes.[1]

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[1] Other courts have had no problem finding defendants guilty under 21 U.S.C. § 841(a)(1) for violating the regulations (primarily 21 C.F.R. § 1306.04). *See United States* v. *Hayes*, 595 F.2d 258, 259 (5th Cir.), *cert. denied*, 100 S. Ct. 138 (1979); *United States* v. *Roya*, 574 F.2d 386, 390 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); *United States* v. *Pastor*, 557 F.2d 930, 939 (2d Cir. 1977); *United States* v. *Rosenberg*, 515 F.2d 190, 196-97 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States* v. *Green*, 511 F.2d 1062, 1069-70 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United*

COUNTS 165-174

Appellants object to counts 165-174 because the indictment failed to charge appellants with distributing schedule IV substances "not in the usual course of professional practice." Appellants claim that pharmacists are exempt from the criminal sanctions of § 841(a)(1) if they dispense drugs in the usual course of professional practice. The facts as alleged do not amount to a crime, appellants argue, as the counts do not allege appellants acted outside the usual course of professional conduct. The government argues the indictment need not charge that the exemption does not apply.

An indictment is sufficient if it contains the elements of the offense charged and fairly informs a defendant of the charge against him and enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense. *Hamling* v. *United States*, 418 U.S. 87, 117 (1974).

The counts in question allege that certain drugs were distributed by unlawfully refilling certain prescriptions. The prescriptions are identified by date, serial number, and issuing doctor. The counts further allege these distributions were in violation of 21 U.S.C. § 841(a)(1). Surely, enough facts are alleged to enable appellants to

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States v. *Larson*, 507 F.2d 385, 386 (9th Cir. 1974); *United States* v. *Bartee*, 479 F.2d 484, 488 (10th Cir. 1973). Further support for our conclusion that Congress intended a violation of the regulations to be unlawful may be found in the legislative history. *See* House Report No. 91-1444, 91st Cong., 2d Session, 1970 U.S. Code Cong. & Admin. News 4566, 4569:

> The bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

plead acquittal or conviction in bar of future prosecutions for the same offense since the precise acts which constitute the offense have been alleged. The only problem is whether by failure to allege the distributions were not in the usual course of professional practice the indictment fails to allege all the elements of the crime.

In *Hamling*, the Court held that as the definition of obscenity was a matter of law, not of fact, the indictment charging use of the mails to carry an obscene book and an obscene advertisement was sufficient even though the indictment did not allege the constitutional components of the definition of obscenity.

In *United States* v. *Ellzey*, 527 F.2d 1306 (6th Cir. 1976), this Court held that an indictment charging the defendant with illegally distributing controlled substances in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2 was sufficient even though it alleged "distribute" rather than "dispense". The Court held that the defendant did distribute rather than dispense as the evidence showed the defendant did not follow generally accepted medical procedures.

The indictments in the present case also charge appellants with illegal distributions in violation of § 841 (a)(1). As a matter of law, a registered doctor is subject to the criminal penalties of § 841(a)(1) if he is not acting within the usual course of professional conduct. *See United States* v. *Moore*, 423 U.S. 122 (1975). Thus, the allegation of distribution in violation of § 841(a)(1) includes the legal definition that the drugs were not dispensed, *i.e.*, distributed in the usual course of professional practice. That counts 165-174 of the indictment do not state this allegation expressly does not render them defective.

II. Jury Instructions

A.

Appellants claim that they did not unlawfully distribute, but lawfully dispensed as authorized by 21 U.S.C. §§ 829(b), 829(c). They claim the government must prove they do not fall within these exceptions to § 841(a)(1) as they introduced evidence that they refilled the prescriptions for the schedule IV drugs upon lawful refill orders of doctors and dispensed the schedule V drugs for lawful medical purposes. They claim they were entitled to have the jury instructed upon §§ 829(b) and 829(c), as well as the statutory definitions of "dispense", "distribute", and "practitioner".

Section 829(b) provides that no schedule IV drug which is a prescription drug may be dispensed without a written or oral prescription. Such prescriptions may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times after the date of the prescription unless renewed by the practioner. Section 829(c) provides that no schedule V drug may be distributed or dispensed other than for a medical purpose.

Section 802(11) defines "distribution" as delivery (other than by administration or dispensing) of a controlled substance. Section 802(10) defines "dispense" to mean the delivery of a controlled substance pursuant to the lawful order of a practitioner to an ultimate user. Section 802(20) defines "practioner" as a physician, pharmacy, (among others) or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Essentially, appellants wanted an instruction that if they delivered the schedule IV drugs in good faith pur-

suant to lawful orders of doctors and delivered the schedule V drugs in good faith for a medical purpose in the usual course of professional practice, they would not be criminally liable under § 841(a)(1).

The District Court instructed the jury that § 841(a)(1) provided:

> Except as authorized . . . it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute . . . a controlled substance.

The court charged that the government must prove beyond a reasonable doubt that the substances described in the indictment were unlawfully distributed. To "distribute" was defined as "to deliver a controlled substance." The court went on to say a controlled substance was distributed "unlawfully" "if such distribution is not authorized by the statute." In instructing when the sale of schedule V drugs was authorized, the court listed the requirements of 21 C.F.R. § 1306.32. When instructing when the refill of a prescription for a schedule IV drug was authorized, the court listed the requirements of 21 C.F.R. § 1306.22.[2] The court nowhere instructed the jury that if appellants were dispensing—that is, filling prescriptions pursuant to lawful orders of practitioners or delivering drugs for good medical purposes in the usual course of professional conduct—they would be exempt from criminal liability under 21 U.S.C. § 841(a)(1).

The Supreme Court in *United States* v. *Moore*, 423 U.S. 122 (1975), held that a registered doctor could be prosecuted under § 841(a)(1) when his activities fell

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[2] What the court read of 21 C.F.R. § 1306.22 imposes the same requirements on refills as § 849(b) except that it adds that any refill beyond the fifth refill must be on a new and separate prescription.

outside the usual course of professional practice. The Court rejected the argument of the D.C. Court of Appeals that registered doctors are exempted from prosecution under § 841(a)(1) by virtue of their status as registered doctors and were only subject to the lesser penalties provided in §§ 842, 843. Implicit in *Moore* is that registered doctors (or other practioners) are exempt from criminal liability under § 841(a)(1) unless they were acting outside the usual course of professional practice. *See United States* v. *Kirk*, 584 F.2d 773, 784 (6th Cir.), *cert. denied*, 439 U.S. 1048 (1978). Thus, a conviction under § 841(a)(1) requires the government to prove beyond a reasonable doubt that the drugs were distributed outside the usual course of professional practice. *See United States* v. *Rogers*, 609 F.2d 834, 839 (5th Cir. 1980); *United States* v. *Hayes*, 595 F.2d 258, 259 & n.2 (5th Cir.), *cert. denied*, 100 S.Ct. 138 (pharmacist) (1979); *United States* v. *King*, 587 F.2d 956, 965 (9th Cir. 1978); *United States* v. *Black*, 512 F.2d 864, 871 (9th Cir. 1975).

In *United States* v. *Carroll*, 518 F.2d 187 (6th Cir. 1975), the defendant requested an instruction that as a doctor he had a right to prescribe controlled substances including Seconal and he would violate § 841(a)(1) only if he prescribed such substances outside the doctor-patient relationship. The District Court refused to so instruct, instead relying upon the language of § 841(a)(1) and the definitions of distribution, dispensing, and practitioner. This Court held the statutory definitions were not sufficient. The defendant was entitled to have the jury instructed that registered doctors are exempt from the provisions of the drug abuse statute when they dispense or prescribe controlled substances in good faith to patients in the regular course of professional practice. In the present case, appellants asked for instructions on the statutory definitions of "dispense" and "practioner"

and for §§ 829(b) and 829(c). They were entitled at least to have the statutory definitions and other relevant sections read. The failure to instruct as to §§ 829(b) and 829(c) and the statutory definitions of "distribute", "dispense", and "practitioner" was prejudicial error.

B.

Appellants also object to the jury instructions in that the judge, when reading § 841(a)(1) to the jury, said distributions of controlled substances were unlawful "except as authorized", without saying as the statute does, "except as authorized by this [subchapter]". The Court finds this objection to be without merit. Six sentences later, the District Court instructed "Under Section 841 (a)(1) of Title 21, United States Code, a controlled substance is distributed 'unlawfully' if such distribution is not authorized by the statute."

C.

Appellants object to the jury instruction that the element of knowledge may be inferred from proof that appellants deliberately closed their eyes to what would otherwise be obvious to them. In *United States* v. *Thomas*, 484 F.2d 909, 912-13 (6th Cir.), *cert. denied*, 414 U.S. 912 (1973), a case in which the defendant was charged with knowingly making false statements in purchasing a handgun, this Court approved an instruction that to find the defendant knowingly made a false statement, the jury need not find the defendant actually read the form or had it read to him "if the jury finds from the evidence beyond a reasonable doubt that the defendant acted with reckless disregard of whether the statements made were true or with a conscious purpose to avoid learning the truth." The deliberate ignorance instruction has also been approved for violations of the Controlled Substances Act. *See United States* v. *Kershman*,

555 F.2d 198, 200-201 (8th Cir.), *cert. denied*, 434 U.S. 892 (1977). The instruction on deliberate ignorance was not erroneous.

III. Evidentiary Issues

A.

Appellants claim that the testimony of Gerald Kopp, a Federal Drug Enforcement Administration investigation officer, invaded the province of the jury when he stated the requirements of federal regulations and what the routine practices of pharmacists should be according to the regulations. They specifically object to his references to the 48-hour rule with respect to selling Robitussin, the requirement that a new and separate prescription be written for refills of schedule IV drugs after the fifth refill of the original prescription, the value of the prescriptions, and the quantity of the substances sold. They challenge his qualifications to testify about any of these matters.

The witness had been a compliance investigator with the Drug Enforcement Administration for over four years and was familiar with the regulations. He testified that he was familiar with the "value" of a prescription (that is, the number of units of drugs authorized under a prescription) and knew how the number of pills dispensed was indicated upon a prescription. The District Court did not err in permitting the witness to testify based upon his experience as a compliance officer.

B.

Appellants object to the admission of exhibits 1-165. Exhibits 1-165 purported to be copies of pages of the over-the-counter exempt ledgers kept by Seelig Pharmacy. Appellants claim these are unauthenticated hearsay. Kopp testified that when he went into Seelig Pharmacy to investigate, he requested the records which are re-

quired to be kept for sales of schedule V drugs. Appellant Seelig handed him the records, which were later seized and from which the copies were made. The identification by Kopp and the admission by Seelig (Rule 801 (1) (2), Fed. R. Evid.) establish that the records were ones of regularly conducted activity which is an exception to the hearsay rule, Rule 803(6), Fed. R. Evid., and were properly authenticated under Rule 901, Fed. R. Evid.

C.

Appellants also object to the admission of exhibits 210, 211, and 212, which are summaries made by Kopp from exhibits 1-165 showing high volume purchasers and the dates when they purchased a schedule V substance. Appellants claim these were irrelevant and prejudicial, since they show a total of 1,409 sales, of which only 32 were mentioned in the indictment. Rule 1006, Fed. R. Evid., provides that the contents of voluminous writings, recordings, or photographs which cannot be conveniently examined in court may be presented in the form of a chart, summary, or calculation. In *United States* v. *Scales*, 594 F.2d 558 (6th Cir.), *cert, denied*, 99 S.Ct. 2168 (1979), this Court held the admission of a summary chart of 161 underlying exhibits was proper. Although the underlying writings could possibly have been examined, the use of the summary was permitted under Rule 1006 as comprehension of the voluminous exhibits would have been difficult and certainly inconvenient. The facts summarized were objective and were stated in a neutral way. The chart was found to be accurate and authentic. Finally, the trial court had given a limiting instruction that the chart was not evidence but was only an aid in evaluating the evidence. In the present case, the underlying documents were numerous and inconvenient to examine. Appellants do not object to the accuracy of the summaries. They do

object to the failure to give a limiting instruction, but the record does not show they asked for such an instruction.

Appellants argue that the relevance of the summaries was outweighed by their prejudice because these exhibits tend to show by the representations of high volume sales that there must have been other violations than those charged. The government claims the high volume shows knowledge and intent. Since these exhibits show only what a close reading of the underlying records also disclose, that is, that certain individuals bought schedule V drugs quite frequently, any prejudice is in the underlying evidence, not in the form of the summary.

D.

Appellants object to the admission of exhibit 213, which purportedly is a sales comparison chart compiled by Columbus Police Officer James Dempsey, comparing the sales of nonexempt schedule V items of Seelig Pharmacy with eight other pharmacies allegedly comparable in size, location, and volume. The two Seelig stores, one of which is located on the east side of Columbus, Ohio and the other on the north side, were compared with an average of four east side stores and an average of four north side stores. In denying a motion in limine and holding that the chart could be admitted as a summary under Rule 1006, the District Court stated:

> The probative value of these charts will depend, of course, on the actual similarity between the stores chosen to comprise the "average" stores and the two Seelig stores. The Court is of the opinion that these matters can be developed properly upon cross-examination without undue confusion to the jury.

The admission of the sales comparison chart was error. The underlying records on which they were based were

not exhibits nor were they made available to appellants. The only records of these other stores examined by Dempsey were the schedule V sales. There was no attempt to compare the stores in terms of total sales. Sergeant Dempsey was not an expert witness. He admitted he was not an economist, statistician, or real estate appraiser. The chart could not therefore be admitted under the exception for the bases of opinion testimony by experts. Rule 703, Fed. R. Evid. He did not know if his allegedly comparable stores operated the same hours. The two Seelig stores were located near a freeway. He testified that he picked, apparently at random, six stores from each area, then did not use two whose volume seemed too low. The record does not show these other stores were the same size, covered the same marketing area, were open the same hours, had pharmacists on duty at all times, had the same access to the public, or, most importantly, charged the same prices—all of which could have significantly affected the volume of sales. Thus, the sales comparison chart is simply irrelevant for failure to establish the comparability of the other stores.

The prosecutor's use of the comparison chart in final argument precludes us from finding its admission harmless error. The prosecutor told the jury that although there were only 165 instances of sales of Robitussin within 48 hours, they could use all the evidence to determine whether the defendants were acting knowingly and intentionally. He mentioned that approximately 18,000 bottles of Robitussin were sold. The trial judge interjected that those were not all unauthorized sales. The prosecutor agreed but commented, "We have not charged a count for every sale". He referred to the sales comparison chart:

> This chart has also been admitted. You can have that and look at it, and you decide what weight you want to put on the fact that Seelig's pharma-

> cies in the red here sold some months over $1,000,-000. Of course, it started out small here at the beginning of time—gradually built up. You decide what weight you want to put on that fact as opposed to the average of four stores in each vicinity . . . . The purpose of this is to show . . . another circumstance to show these people must have known what they were doing.

This Court has previously considered comparisons of distributions of controlled substances in two cases. In *Kirk, supra,* to prove the defendant had the requisite knowledge of the conspiracy and the criminal intent, the government introduced the testimony of Richard Ross, who was charged to investigate all the pharmacies in a tri-county area. In this investigation, he found that drugstores were selling an unreasonable quantity of schedule II drugs prescribed by the defendant. Apparently at one pharmacy, 90% of the schedule II drugs were prescribed by the defendant, whereas all the other physicians comprised the remaining 10%. The Court found that this was evidence of intent. In *Ellzey, supra,* the Drug Enforcement Administration surveyed schedule II prescriptions from six drugstores. Of 39,000 prescriptions from 152 doctors and dentists in a 22-month period, 29,000 were written by the defendant and all but 200 of these were for amphetemines or amphetemine-type drugs. The 29,000 prescriptions were admitted to show intent and wilfulness. The Court ruled the admission was not error.

Kirk and *Ellzey* establish that evidence of high volume may be used to show intent and willfulness. However, in each of those cases, the comparison chart was relevant—the defendants were compared with all other doctors whose patients used the same pharmacies. In the present case, the jury was invited to make the same inference as was made in *Kirk* and *Ellzey,* that the large volume

compared to other pharmacies indicates knowledge and intent, but the underlying figures were not truly comparable in the absence of a comparison of total sales or other appropriate basis. The exhibit suggested the jury make an inference of guilt that the exhibit did not support. Thus, the admission of the exhibit was prejudicial error.

E.

Appellants also object to the trial court's refusal to allow Jack R. Lawry, a former narcotics inspector and investigator for the Ohio State Board of Pharmacy, to testify as to the custom of pharmacists regarding the sales of over-the-counter exempt drugs. Appellants proffered that he would also testify that it would be utterly impossible for a busy pharmacist to go back into the ledger to see if there had been a sale of exempt items to the same person within 48 hours. The prosecutor responds that testimony would be beyond the witness' expertise and that it would be irrelevant as appellants were not charged with operating outside the usual course of professional conduct.

Lawry was as qualified as Kopp, who was allowed to testify as to what the routine procedure of pharmacists should be under the regulations. That the indictment did not explicitly charge appellants with acting outside the usual course of professional conduct is immaterial—a violation of § 841(a)(1) necessarily implies that a registered doctor or other practitioner is acting outside the usual course of professional conduct. Lawry's testimony was relevant and should have been admitted.

IV. Motion for Acquittal

The trial court properly denied appellant's motion for judgment of acquittal. The documentary evidence discloses repeated occasions where more than four ounces of a schedule V drug was sold to the same person within

a 48 hour period. With respect to the felony counts, several physicians testified that their records failed to disclose oral authorizations for renewal of prescriptions and that it was their practice to record such oral authorizations. At least one witness denied receiving any refills of a prescription which Seelig Pharmacy records showed had been refilled several times. After review of the entire record, we conclude that there was sufficient evidence of intent; the motion for acquittal was properly denied.

The prejudicial errors found by this Court require that defendants be given a new trial. The judgments are reversed and the cases remanded for proceedings in accordance with this opinion.

C. Judgment Entry of May 8, 1980

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Nos. 79-5232
79-5233
79-5234

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

RICHARD SEELIG, TERRY HAWKINS,
and DONALD PRIMMER,
Defendants-Appellants.

Before: KENNEDY and JONES, Circuit Judges, and PHILLIPS, Senior Circuit Judge.

JUDGMENT

APPEAL from the United States District Court for the Southern District of Ohio.

THIS CAUSE came on to be heard on the record from the United States District Court for the Southern District of Ohio and was argued by counsel.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the judgments of the said District Court in these causes be and the same are hereby reversed and remanded for further proceedings.

No costs taxed.

ENTERED BY ORDER OF THE COURT.

/s/ [Illegible]
Clerk
A True Copy.
Attest:

/s/ Audrey Crockett
Deputy Clerk

Issued as Mandate:
May 30, 1980

COSTS: NONE

Filing fee .....$

Printing .....$
Total .....$

D. Judgments and Probation Commitment Orders of June 15, 1979 In the United States District Court for the Southern District of Ohio, Eastern Division

United States of America vs.

JUN 15 2 30 PM '79
U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

United States District Court for the Southern District of Ohio

DEFENDANT: RICHARD SEELIG — DOCKET NO.: Cr-2-79-6 (1)

JUDGMENT AND PROBATION/COMMITMENT ORDER

COUNSEL

In the presence of the attorney for the government the defendant appeared in person on this date — MONTH 6 DAY 15 YEAR 79

[ ] WITHOUT COUNSEL However the court advised defendant of right to counsel and asked whether defendant desired to have counsel appointed by the court and the defendant thereupon waived assistance of counsel.

[X] WITH COUNSEL Eugene L. Matan (Name of counsel)

PLEA

[ ] GUILTY, and the court being satisfied that there is a factual basis for the plea, [ ] NOLO CONTENDERE, [X] NOT GUILTY

FILED
JUN 18 1979
CLERK U.S. DISTRICT COURT

FINDING & JUDGMENT

There being a [ ] verdict of [ ] NOT GUILTY. Defendant is discharged [X] GUILTY.

Defendant has been convicted as charged of the offense(s) of of knowingly distribute Schedule V Controlled substance. In violation of Title 21 United States Code, Section 841(a)(1).---Counts 2,12,13,14,30,39,40,57,58,62,79,80,82, 122,123,135,137,142,143 and 144. Did knowingly distribute Schedule IV Controlled Substance. In violation of Title 21 United States Code, Section 841(a)(1).---Counts 167,168,169,170,171,172,173 and 174.

SENTENCE OR PROBATION ORDER

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is hereby fined the sum of Five Thousand ($5,000.00)dollars on Count # 2 of the Indictment. It Is The Further Judgment of the Court that the defendant be fined the sum of Five Hundred ($500.00)dollars each on Counts 12,13,14,30,39,40, 57,58,62,79,80,82,122,123,135,137,142,143 and 144, and that the payment of $500.00 on each of these Counts be suspended.
It Is The Further Judgment of the Court that the defendant be fined the the sum of Five Thousand ($5,000.00)dollars on Count # 167 of the Indictment.
It Is Ther Further Judgment of the Court that the defendant be fined th sum of Five Hundred ($500.00)dollars each on Counts 168,169,170,171, 172,173 and 174, and that the payment of $500.00 on each of these Count be suspended.

SPECIAL CONDITIONS OF PROBATION

It Is The Further Judgment of the Court that RICHARD SEELIG is hereby committed to the custody of the Attorney General of the United States o his authorized representative for imprisonment for a period of Three (3 years on Count # 167 and that the service of such sentence be suspended and that RICHARD SEELIG be and he is hereby placed on probation for a period of Three (3) years.

ADDITIONAL CONDITIONS OF PROBATION

It Is The Further Judgment of the Court that RICHARD SEELIG is hereby committed to the custody of the Attorney General of the United States or his authorized representative for imprisonment for a period of Three (3) years each on Counts 168,169, 170,171, (SEE ATTACHED SHEET)

In addition to the special conditions of probation imposed above, it is hereby ordered that the general conditions of probation set out on the reverse side of this judgment be imposed. The Court may change the conditions of probation, reduce or extend the period of probation, and at any time during the probation period or within a maximum probation period of five years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.

COMMITMENT RECOMMENDATION

The court orders commitment to the custody of the Attorney General and recommends,

It is ordered that the Clerk deliver a certified copy of this judgment and commitment to the U.S. Marshal or other qualified officer.

SIGNED BY

[X] U.S. District Judge

[ ] U.S. Magistrate

Joseph P. Kinneary

Date June 15, 1979

172,173 and 174, such sentences to be served concurrently with each other and concurrently with the sentence imposed in Count # 167, and that the service of such sentences imposed in Counts 168,169,170, 171,172,173 and 174 be suspended and that RICHARD SEELIG be and he is hereby placed on probation for a period of Three (3) years.

It Is The Further Judgment of the Court that the schedule of payments for the fine imposed herein will be subject to the further order of the Court at the appropriate time.

SIGNED BY
[X] U.S. District Judge
[ ] U.S. Magistrate

Date June 15 1979

United States of America vs.

FILED

JOHN D. LYTER, CLERK

JUN 15 2 29 PM '79

U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

United States District Court for Southern District of Ohio

DEFENDANT: TERRY HAWKINS — DOCKET NO.: Cr-2-79-6 (2)

JUDGMENT AND PROBATION/COMMITMENT ORDER

(5/75)

COUNSEL

In the presence of the attorney for the government the defendant appeared in person on this date — MONTH: 6 DAY: 15 YEAR: 79

[ ] WITHOUT COUNSEL However the court advised defendant of right to counsel and asked whether defendant desired to have counsel appointed by the court and the defendant thereupon waived assistance of counsel.

[X] WITH COUNSEL Eugene L. Matan (Name of counsel)

PLEA

[ ] GUILTY, and the court being satisfied that there is a factual basis for the plea, [ ] NOLO CONTENDERE, [X] NOT GUILTY

FINDING & JUDGMENT

There being a [ ] jury [ ] court verdict of [ ] NOT GUILTY. Defendant is discharged [X] GUILTY.

JUN 18 1979

U. S. ATTORNEY

Defendant has been convicted as charged of the offense(s) of knowingly distribute Schedule V Controlled Substance. In violation of Title 21 United States Code, Section 841(a)(1).---Counts 10,26,76,92,121 and 154. Did knowingly distribute Schedule IV Controlled Substance. In violation of Title 21 United States Code, Section 841(a)(1).---Counts 168,169,170,171,172, 173 and 174.

SENTENCE OR PROBATION ORDER

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is hereby ~~committed to the custody of the Attorney General~~ fined the sum of Five Thousand ($5,000.00)dollars on Count # 10 of the Indictment.

It Is The Further Judgment of the Court that the defendant is hereby fined the sum of Five Hundred ($500.00)dollars each on Counts 26,76, 92,121 and 154 and that the payment of $500.00 on each of these Counts be suspended.

It Is The Further Judgment of the Court that TERRY HAWKINS is hereby fined the sum of Five Thousand ($5,000.00)dollars on Count # 168 of of the Indictment.

SPECIAL CONDITIONS OF PROBATION

It Is The Further Judgment of the Court that the defendant is hereby fined the sum of Five Hundred ($500.00)dollars each on Counts 169,170, 171,172,173 and 174 and that the payment of $500.00 on each of these Counts be suspended.

It Is The Further Judgment of the Court that TERRY HAWKINS is hereby committed to the custody of the Attorney General of the United States or his authorized representative for imprisonment for a period of Three (3) years on Count # 168 and that the service of such sentence be suspended and that TERRY HAWKINS be and he is herby placed on probation for aperiod of Three (3) years.

ADDITIONAL CONDITIONS OF PROBATION

It Is The Further Judgment of the Court that TERRY HAWKINS is hereby committed to the custody of the Attorney General of the United Sates or his authorized representative for imprisonment (SEE ATTACHED SHEET)

In addition to the special conditions of probation imposed above, it is hereby ordered that the general conditions of probation set forth on the reverse side of this judgment be imposed. The Court may change the conditions of probation, reduce or extend the period of probation, and at any time during the probation period or within a maximum probation period of five years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.

COMMITMENT RECOMMENDATION

The court orders commitment to the custody of the Attorney General and recommends,

It is ordered that the Clerk deliver a certified copy of this judgment and commitment to the U.S. Marshal or other qualified officer.

SIGNED BY

[X] U.S. District Judge

[ ] U.S. Magistrate

Joseph P. Kinneary

Date June 15, 1979

for a period of Three (3) years each on Counts 169,170,171,172,173 and 174, such sentences to be served concurrently with each other and concurrently with the sentence imposed on Count # 168, and that the service of such sentences imposed in Counts 169,170,171,172,173 and 174 be suspended and that TERRY HAWKINS be and he is hereby placed on probation for a period of Three (3) years.

It Is The Further Judgment of the Court that the schedule of payments for the fine imposed herebin will be subject to the further order of the Court at the appropriate time.

DATION

SIGNED BY
[X] U.S. District Judge
[ ] U.S. Magistrate

James P. Kinneary

Date June 18, 1979

United States of America vs.

FILED
JOHN P. LYTER, CLERK
JUN 15 2 29 PM '79
U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

United States District Court for Southern District of Ohio

DEFENDANT: DONALD PRIMMER — DOCKET NO. Cr-2-79-6 (3)

JUDGMENT AND PROBATION/COMMITMENT ORDER

COUNSEL

In the presence of the attorney for the government the defendant appeared in person on this date — MONTH 6 DAY 15 YEAR 79

[ ] WITHOUT COUNSEL (However the court advised defendant of right to counsel and asked whether defendant desired to have counsel appointed by the court and the defendant thereupon waived assistance of counsel.)

[X] WITH COUNSEL — Eugene L. Matan (Name of counsel)

PLEA

[ ] GUILTY, and the court being satisfied that there is a factual basis for the plea, [ ] NOLO CONTENDERE, [X] NOT GUILTY

FINDING & JUDGMENT

There being a [ ] verdict of [ ] NOT GUILTY. Defendant is discharged [X] GUILTY.

JUN 16 1979
U. S. ATTORNEY
COLUMBUS, OHIO

Defendant has been convicted as charged of the offense(s) of knowingly distribute Schedule V Controlled Substance. In violation of Title 21 United States Code, Section 841(a)(1)---Counts 73,74,95,110,112,124,125,132,133,136,138, 139,140,141,145,146 and 152. Did knowingly distribute Schedule IV Controlled Substance. In violation of Title 21 United States Code. Section 841(a)(1).---Counts 168,169,171,172 and 174.

SENTENCE OR PROBATION ORDER

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is hereby ~~XXXX

a period of Three (3) years each on Counts 169,171,172 and 174, such sentences to be served concurrently with each other and concurrently with the sentence imposed in Count # 168, and that the service of such sentences imposed in Counts 169,171,172 and 174 be suspended and that DONALD PRIMMER be and he is hereby placed on probation for a period of Three (3) years.

It Is The Further Judgment of the Court that the schedule of payments for the fine imposed herein will be subject to the further order of the Court at the appropriate time.

SIGNED BY
U.S. District Judge
U.S. Magistrate

Thomas P. Kennearey

Date June 15, 1979

E. Order Extending Time to File Petition for Writ of Certiorari

SUPREME COURT OF THE UNITED STATES

No. A-1029

RICHARD SEELIG, TERRY HAWKINS
and DONALD PRIMMER,
Petitioners,

v.

UNITED STATES

ORDER EXTENDING TIME TO FILE PETITION FOR WRIT OF CERTIORARI

UPON CONSIDERATION of the application of counsel for petitioner(s),

IT IS ORDERED that the time for filing a petition for writ of certiorari in the above-entitled cause be, and the same is hereby, extended to and including July 7, 1980.

/s/ Potter Stewart
Associate Justice of the
Supreme Court of the
United States

Dated this 27th day of May, 1980.

Supreme Court, U. S.
FILED
AUG 29 1980
MICHAEL RODAK, JR., CLERK

No. 80-23

In the Supreme Court of the United States

OCTOBER TERM, 1979

RICHARD SEELIG, TERRY HAWKINS AND DONALD PRIMMER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

WADE H. McCREE, JR.
Solicitor General

PHILIP B. HEYMANN
Assistant Attorney General

VINCENT L. GAMBALE
Attorney

Department of Justice
Washington, D.C. 20530
(202) 633-2217

In the Supreme Court of the United States

OCTOBER TERM, 1979

No. 80-23

RICHARD SEELIG, TERRY HAWKINS AND DONALD PRIMMER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

QUESTIONS PRESENTED

1. Whether petitioners were properly prosecuted under 21 U.S.C. 841(a)(1) for violating regulations promulgated by the Attorney General under the Controlled Substances Act, 21 U.S.C. 801 *et seq.*

2. Whether a government witness was improperly allowed to testify as to legal conclusions.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 19a-36a) is reported at 622 F. 2d 207.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1980. Mr. Justice Stewart extended the time for filing a petition for a writ of certiorari to and including July 7, 1980, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Southern District of Ohio, petitioners, three registered pharmacists, were convicted on multiple misdemeanor counts of selling four-ounce bottles of cough medicine containing codeine (a schedule V controlled substance) to the same person within a 48-hour period, in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.32(b), and on multiple felony counts of refilling prescriptions for Valium and Darvon (schedule IV controlled substances) without physician authorization, in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.22(a) and 1306.23.[1] Petitioners Seelig and Hawkins were each sentenced to three-year terms of imprisonment, suspended in favor of three years' probation, and to fines totaling $10,000. Petitioner Primmer received the same sentences, except that his fines amounted to $5,000 (Pet. App. 43a-44a). On appeal, the court of appeals found the

[1]Petitioner Seelig was convicted on 19 misdemeanor counts and eight felony counts (Pet. App. 39a). Petitioner Hawkins was convicted on six misdemeanor counts and seven felony counts (*id.* at 41a). Petitioner Primmer was convicted on 18 misdemeanor counts and five felony counts (*id.* at 43a).

evidence sufficient to sustain petitioners' convictions, but it remanded for a new trial on the ground that the trial judge erred in admitting certain evidence and in giving certain instructions to the jury (Pet. App. 19a-36a).

The trial evidence showed that petitioners Seelig and Hawkins were co-owners of Seelig Pharmacies, Inc., which operated two retail drugstores in Columbus, Ohio. All three petitioners are registered pharmacists who worked in those stores. The pharmacies' record books for April and May 1978, which were obtained in connection with a DEA audit, showed "repeated occasions where more than four ounces of [codeine-based cough medicine] was sold to the same person within a 48 hour period" (Pet. App. 35a-36a). Five customers, including two undercover police officers, testified that they had made such purchases, including repeat purchases in the same store on the same day (II Tr. 25-37, 61-77, 88-105). Moreover, records of the pharmaceutical wholesalers serving the Selig stores showed that the stores had purchased unusually large amounts of codeine-based cough preparations (Gov. Exhs. 215-217).

Petitioners' records also showed that they had refilled or renewed Valium and Darvon prescriptions without authorization by the prescribing physician. While petitioners presented testimony to show that they routinely renewed prescriptions upon oral authorization (Pet. 7), several prescribing physicians testified that "their records failed to disclose oral authorizations for renewal of prescriptions and that it was their practice to record such oral authorizations" (Pet. App. 36a).

ARGUMENT

In *United States* v. *Grimaud*, 220 U.S. 506, 517-519 (1911), this Court held that a person may not be prosecuted for violating an administrative regulation

unless the underlying statute authorizes criminal prosecution for such a violation. The court below properly rejected petitioners' contention (Pet. 8-18) that the Controlled Substances Act provides no authority for criminal prosecutions based on violations of the regulations at issue here.[2] In an opinion upon which we rely in the main, the court of appeals held (Pet. App. 23a):

> The combination of [21 U.S.C.] §829(c) and §822(b)[3] thus requires a person to dispense or distribute a schedule V drug for a medical purpose and to be within the authority of their registration as determined by the Attorney General. Section 822(a) requires every person who distributes or dispenses controlled substances to register with the Attorney General. Section 821 authorizes the Attorney General to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. Section 871(b) authorizes the

---

[2]At the outset, we note that the petitioners are in essentially the same position as if the district court had denied a motion to dismiss this indictment. Petitioners have been granted a new trial and may be acquitted. If petitioners are convicted, they will be free to raise this issue at that time.

[3]Section 829(c) provides:

> No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

Section 822(b) provides:

> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

> Attorney General to promulgate and enforce rules, regulations, and procedures that he deems necessary for the efficient execution of his functions.
>
> Although Congress was not as clear in this statute as in the one involved in *Grimaud*, this Court is satisfied that the statute does expressly, albeit in a convoluted fashion, provide that a violation of the promulgated rules constitutes an unlawful act under the Controlled Substances Act.[4]

The court also correctly observed (Pet. App. 23a-24a n.1), that

> [o]ther courts have had no problem finding defendants guilty under 21 U.S.C. §841(a)(1) for violating the regulations (primarily 21 C.F.R. §1306.04). See *United States* v. *Hayes*, 595 F. 2d 258, 259 (5th Cir.), *cert. denied*, 100 S. Ct. 138 (1979); *United States* v. *Roya*, 574 F. 2d 386, 390 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); *United States* v. *Pastor*, 557 F. 2d 930, 939 (2d Cir. 1977) *United States* v. *Rosenberg*, 515 F. 2d 190, 196-97 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States* v. *Green*, 511 F. 2d 1062, 1067-70 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975); *United States* v. *Larson*, 507 F. 2d 385, 386 (9th Cir. 1974); *United States* v. *Bartee*, 479 F. 2d 484, 488 (10th Cir. 1973).[5]

Petitioners attempt to avoid the weight of those decisions with the observation (Pet. 12) that those

---

[4]Section 841(a)(1) provides in relevant part:

> (a) Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; * * *.

[5]Petitioners do not contend that the decision below conflicts with the decision of any other court of appeals.

prosecutions involved violations of 21 C.F.R. 1306.04, while this case involves violations of 21 C.F.R. 1302.22, 1306.23 and 1306.32. Petitioners assert that 21 C.F.R. 1306.04 presents a special case because it merely "mimics the statute" and does not "expand" the reach of the statute. That contention is ill-founded because 21 C.F.R. 1306.04 "mimics the statute" no more than do the regulations at issue here. Section 1306.04 provides that prescription drugs may not be dispensed except for a "legitimate medical purpose," a standard that the regulation also explains, and one that is not specifically set out in the statute. To be sure, the regulations here set more precise guidelines governing the dispensation of controlled drugs.[6] But, as the Seventh Circuit said in *United States* v. *Green*, 511 F. 2d 1062, 1070 (7th Cir.), cert. denied, 423 U.S. 1031 (1975), in upholding a conviction based on a violation of 21 C.F.R. 1306.04, "more precise regulations are desirable as to what physicians [or pharmacists] may or may not do" with respect to the dispensation of controlled drugs.

---

[6]21 C.F.R. 1306.32(b) provides in relevant part that "[n]ot more than 24 dosage units [four ounces] of [codeine-based medicine] may be dispensed at retail to the same purchaser in any given 48-hour period."

21 C.F.R. 1306.22(a) provides in relevant part that "[n]o prescription for [schedule IV drugs] shall be filled or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. * * * Additional [schedule IV drugs] may only be authorized by a prescribing practitioner through issuance of * * * a new and separate prescription."

21 C.F.R. 1306.23 provides in relevant part that partial filling of a prescription for a schedule IV drug is permissible providing "(a) [e]ach partial filling is recorded in the same manner as a refilling, (b) [t]he total quantity dispensed * * * does not exceed the total quantity prescribed, and (c) [n]o dispensing occurs after 6 months after the date on which the prescription was issued."

At all events, the statutory language and the legislative history support the authority of the Attorney General to promulgate regulations that "fill up the details" rather than simply "mimic the statute,"[7] and the power of Congress to confer that authority is equally clear. As the Court said in *Grimaud*, *supra*, 220 U.S. at 517:

> From the beginning of the Government various acts have been passed conferring upon executive officers power to make rules and regulations—not for the government of their departments, but for administering the laws which did govern. None of these statutes could confer legislative power. But when Congress had legislated and indicated its will, it could give to those who were to act under such general provisions "power to fill up the details" by the establishment of administrative rules and regulations, the violation of which could be punished by fine or imprisonment fixed by Congress, or by penalties fixed by Congress or measured by the injury done.

Moreover, the Attorney General's unquestioned authority to determine which drugs should be controlled[8] underscores his attendant authority to promulgate regulations, such as those at issue here, that merely set guidelines for the lawful dispensation of drugs that he has designated as controlled substances.

---

[7]See H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. 38, 51 (1970) (the statute "authorizes the Attorney General to promulgate rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of substances covered by the act * * * and it authorizes him to promulgate rules and regulations for the efficient execution of his functions under title II [of the act].")

[8]See *United States* v. *Barron*, 594 F. 2d 1345, 1352-1353 (10th Cir.), cert. denied, 441 U.S. 951 (1979); *United States* v. *Dunbar*, 590 F. 2d

Nor is there any merit to petitioners' contention (Pet. 12-13) that 21 C.F.R. 1306.32 is arbitrary or "totally unrelated to the notion of 'medical purpose' " as that term is used in 21 U.S.C. 829(c). The regulation merely reflects the obvious fact that a person will rarely, if ever, have a legitimate medical need to consume more than one four-ounce bottle of codeine-based cough medicine within a two-day period.[9] Moreover, the trial evidence showed that a substantial amount of the cough medicine dispensed by petitioners was consumed not for medical purposes, but for purposes of getting "high" (II Tr. 25-26).[10]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

PHILIP B. HEYMANN
Assistant Attorney General

VINCENT L. GAMBALE
Attorney

AUGUST 1980

1340, 1342; *United States* v. *Roya*, 574 F. 2d 386, 392 (7th Cir. 1978); *United States* v. *Davis*, 564 F. 2d 840, 843-844 (9th Cir. 1977), cert. denied, 434 U.S. 1015 (1978); *United States* v. *Pastor*, *supra*, 557 F. 2d 930, 941 (2d Cir. 1977).

[9]FDA guidelines provide that the label on a four-ounce bottle of codeine-based cough medicine may not recommend a *maximum* adult dosage exceeding four ounces within a 48-hour period. See *Physicians Desk Reference* 1444 (34th ed. 1980).

[10]Petitioners' unrelated contention (Pet. 18-27) that the district court erred in allowing a DEA investigator "to testify as to his personal opinion of the Federal Law" was properly rejected by the court of appeals (Pet. App. 30a). In any event, that issue does not warrant review because it relates to the specific content of a witness's trial testimony, and petitioners have now been granted a new trial.